

108TH CONGRESS  
1ST SESSION

# S. 54

To amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals.

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## IN THE SENATE OF THE UNITED STATES

JANUARY 7, 2003

Mr. SCHUMER (for himself, Mr. MCCAIN, Mr. EDWARDS, Ms. COLLINS, Mr. KENNEDY, Mr. MILLER, Mr. JOHNSON, Mrs. CLINTON, Mr. KOHL, Mr. FEINGOLD, Ms. STABENOW, Mr. DASCHLE, Mr. NELSON of Florida, Mr. ROCKEFELLER, Mr. LEAHY, Mr. REED, Mr. PRYOR, Mr. DURBIN, and Mr. DORGAN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

### 3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Greater Access to Af-  
5 fordable Pharmaceuticals Act of 2003”.

### 6 **SEC. 2. FINDINGS; PURPOSES.**

7 (a) FINDINGS.—Congress finds that—

1           (1) prescription drug costs are increasing at an  
2           alarming rate and are a major worry of American  
3           families and senior citizens;

4           (2) enhancing competition between generic drug  
5           manufacturers and brand-name manufacturers can  
6           significantly reduce prescription drug costs for  
7           American families;

8           (3) the pharmaceutical market has become in-  
9           creasingly competitive during the last decade be-  
10          cause of the increasing availability and accessibility  
11          of generic pharmaceuticals, but competition must be  
12          further stimulated and strengthened;

13          (4) the Federal Trade Commission has discov-  
14          ered that there are increasing opportunities for drug  
15          companies owning patents on brand-name drugs and  
16          generic drug companies to enter into private finan-  
17          cial deals in a manner that could restrain trade and  
18          greatly reduce competition and increase prescription  
19          drug costs for consumers;

20          (5) generic pharmaceuticals are approved by the  
21          Food and Drug Administration on the basis of sci-  
22          entific testing and other information establishing  
23          that pharmaceuticals are therapeutically equivalent  
24          to brand-name pharmaceuticals, ensuring consumers

1 a safe, efficacious, and cost-effective alternative to  
2 brand-name innovator pharmaceuticals;

3 (6) the Congressional Budget Office estimates  
4 that—

5 (A) the use of generic pharmaceuticals for  
6 brand-name pharmaceuticals could save pur-  
7 chasers of pharmaceuticals between  
8 \$8,000,000,000 and \$10,000,000,000 each  
9 year; and

10 (B) generic pharmaceuticals cost between  
11 25 percent and 60 percent less than brand-  
12 name pharmaceuticals, resulting in an esti-  
13 mated average savings of \$15 to \$30 on each  
14 prescription;

15 (7) generic pharmaceuticals are widely accepted  
16 by consumers and the medical profession, as the  
17 market share held by generic pharmaceuticals com-  
18 pared to brand-name pharmaceuticals has more than  
19 doubled during the last decade, from approximately  
20 19 percent to 43 percent, according to the Congres-  
21 sional Budget Office;

22 (8) expanding access to generic pharmaceuticals  
23 can help consumers, especially senior citizens and  
24 the uninsured, have access to more affordable pre-  
25 scription drugs;

1           (9) Congress should ensure that measures are  
2       taken to effectuate the amendments made by the  
3       Drug Price Competition and Patent Term Restora-  
4       tion Act of 1984 (98 Stat. 1585) (referred to in this  
5       section as the “Hatch-Waxman Act”) to make ge-  
6       neric drugs more accessible, and thus reduce health  
7       care costs; and

8           (10) it would be in the public interest if patents  
9       on drugs for which applications are approved under  
10      section 505(c) of the Federal Food, Drug, and Cos-  
11      metic Act (21 U.S.C. 355(c)) were extended only  
12      through the patent extension procedure provided  
13      under the Hatch-Waxman Act rather than through  
14      the attachment of riders to bills in Congress.

15      (b) PURPOSES.—The purposes of this Act are—

16           (1) to increase competition, thereby helping all  
17      Americans, especially seniors and the uninsured, to  
18      have access to more affordable medication; and

19           (2) to ensure fair marketplace practices and  
20      deter pharmaceutical companies (including generic  
21      companies) from engaging in anticompetitive action  
22      or actions that tend to unfairly restrain trade.

1 **SEC. 3. FILING OF PATENT INFORMATION WITH THE FOOD**  
2 **AND DRUG ADMINISTRATION.**

3 (a) FILING AFTER APPROVAL OF AN APPLICA-  
4 TION.—

5 (1) IN GENERAL.—Section 505 of the Federal  
6 Food, Drug, and Cosmetic Act (21 U.S.C. 355) (as  
7 amended by section 9(a)(2)(B)(ii)) is amended in  
8 subsection (c) by striking paragraph (2) and insert-  
9 ing the following:

10 “(2) PATENT INFORMATION.—

11 “(A) IN GENERAL.—Not later than the  
12 date that is 30 days after the date of an order  
13 approving an application under subsection (b)  
14 (unless the Secretary extends the date because  
15 of extraordinary or unusual circumstances), the  
16 holder of the application shall file with the Sec-  
17 retary the patent information described in sub-  
18 paragraph (C) with respect to any patent—

19 “(i)(I) that claims the drug for which  
20 the application was approved; or

21 “(II) that claims an approved method  
22 of using the drug; and

23 “(ii) with respect to which a claim of  
24 patent infringement could reasonably be  
25 asserted if a person not licensed by the

owner engaged in the manufacture, use, or sale of the drug.

“(B) SUBSEQUENTLY ISSUED PATENTS.—

In a case in which a patent described in subparagraph (A) is issued after the date of an order approving an application under subsection (b), the holder of the application shall file with the Secretary the patent information described in subparagraph (C) not later than the date that is 30 days after the date on which the patent is issued (unless the Secretary extends the date because of extraordinary or unusual circumstances).

“(C) PATENT INFORMATION.—The patent information required to be filed under subparagraph (A) or (B) includes—

“(i) the patent number;

“(ii) the expiration date of the patent;

“(iii) with respect to each claim of the patent—

“(I) whether the patent claims the drug or claims a method of using the drug; and

“(II) whether the claim covers—

“(aa) a drug substance;

1 “(bb) a drug formulation;

2 “(cc) a drug composition; or

3 “(dd) a method of use;

4 “(iv) if the patent claims a method of  
5 use, the approved use covered by the claim;

6 “(v) the identity of the owner of the  
7 patent (including the identity of any agent  
8 of the patent owner); and

9 “(vi) a declaration that the applicant,  
10 as of the date of the filing, has provided  
11 complete and accurate patent information  
12 for all patents described in subparagraph  
13 (A).

14 “(D) PUBLICATION.—On filing of patent  
15 information required under subparagraph (A)  
16 or (B), the Secretary shall—

17 “(i) immediately publish the informa-  
18 tion described in clauses (i) through (iv) of  
19 subparagraph (C); and

20 “(ii) make the information described  
21 in clauses (v) and (vi) of subparagraph (C)  
22 available to the public on request.

23 “(E) CIVIL ACTION FOR CORRECTION OR  
24 DELETION OF PATENT INFORMATION.—

1           “(i) IN GENERAL.—A person that has  
 2           filed an application under subsection (b)(2)  
 3           or (j) for a drug may bring a civil action  
 4           against the holder of the approved applica-  
 5           tion for the drug seeking an order requir-  
 6           ing that the holder of the application  
 7           amend the application—

8                   “(I) to correct patent information  
 9                   filed under subparagraph (A); or

10                  “(II) to delete the patent infor-  
 11                  mation in its entirety for the reason  
 12                  that—

13                   “(aa) the patent does not  
 14                   claim the drug for which the ap-  
 15                   plication was approved; or

16                   “(bb) the patent does not  
 17                   claim an approved method of  
 18                   using the drug.

19           “(ii) LIMITATIONS.—Clause (i) does  
 20           not authorize—

21                   “(I) a civil action to correct pat-  
 22                   ent information filed under subpara-  
 23                   graph (B); or

24                   “(II) an award of damages in a  
 25                   civil action under clause (i).



“(F) NO CLAIM FOR PATENT INFRINGEMENT.—An owner of a patent with respect to which a holder of an application fails to file information on or before the date required under subparagraph (A) or (B) shall be barred from bringing a civil action for infringement of the patent against a person that—

“(i) has filed an application under subsection (b)(2) or (j); or

“(ii) manufactures, uses, offers to sell, or sells a drug approved under an application under subsection (b)(2) or (j).”.

(2) TRANSITION PROVISION.—

(A) FILING OF PATENT INFORMATION.—

Each holder of an application for approval of a new drug under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) that has been approved before the date of enactment of this Act shall amend the application to include the patent information required under the amendment made by paragraph (1) not later than the date that is 30 days after the date of enactment of this Act (unless the Secretary of Health and Human

Services extends the date because of extraordinary or unusual circumstances).

(B) NO CLAIM FOR PATENT INFRINGEMENT.—An owner of a patent with respect to which a holder of an application under subsection (b) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) fails to file information on or before the date required under subparagraph (A) shall be barred from bringing a civil action for infringement of the patent against a person that—

(i) has filed an application under subsection (b)(2) or (j) of that section; or

(ii) manufactures, uses, offers to sell, or sells a drug approved under an application under subsection (b)(2) or (j) of that section.

(b) FILING WITH AN APPLICATION.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

(1) in subsection (b)(2)—

(A) in subparagraph (A), by striking “and” at the end;

(B) in subparagraph (B), by striking the period at the end and inserting “; and”; and

1 (C) by adding at the end the following:

2 “(C) with respect to a patent that claims  
3 both the drug and a method of using the drug  
4 or claims more than 1 method of using the drug  
5 for which the application is filed—

6 “(i) a certification under subpara-  
7 graph (A)(iv) on a claim-by-claim basis;  
8 and

9 “(ii) a statement under subparagraph  
10 (B) regarding the method of use claim.”;  
11 and

12 (2) in subsection (j)(2)(A), by inserting after  
13 clause (viii) the following:

14 “With respect to a patent that claims both the drug and  
15 a method of using the drug or claims more than 1 method  
16 of using the drug for which the application is filed, the  
17 application shall contain a certification under clause  
18 (vii)(IV) on a claim-by-claim basis and a statement under  
19 clause (viii) regarding the method of use claim.”.

20 **SEC. 4. LIMITATION OF 30-MONTH STAY TO CERTAIN PAT-**  
21 **ENTS.**

22 (a) ABBREVIATED NEW DRUG APPLICATIONS.—Sec-  
23 tion 505(j)(5) of the Federal Food, Drug, and Cosmetic  
24 Act (21 U.S.C. 355(j)(5)) is amended—

25 (1) in subparagraph (B)—

1 (A) in clause (iii)—

2 (i) by striking “(iii) If the applicant  
3 made a certification described in subclause  
4 (IV) of paragraph (2)(A)(vii),” and insert-  
5 ing the following:

6 “(iii) SUBCLAUSE (IV) CERTIFICATION  
7 WITH RESPECT TO CERTAIN PATENTS.—If  
8 the applicant made a certification de-  
9 scribed in paragraph (2)(A)(vii)(IV) with  
10 respect to a patent (other than a patent  
11 that claims a process for manufacturing  
12 the listed drug) for which patent informa-  
13 tion was filed with the Secretary under  
14 subsection (c)(2)(A),”; and

15 (ii) by adding at the end the fol-  
16 lowing: “The 30-month period provided  
17 under the second sentence of this clause  
18 shall not apply to a certification under  
19 paragraph (2)(A)(vii)(IV) made with re-  
20 spect to a patent for which patent informa-  
21 tion was filed with the Secretary under  
22 subsection (c)(2)(B).”;

23 (B) by redesignating clause (iv) as clause  
24 (v); and

1 (C) by inserting after clause (iii) the fol-  
2 lowing:

3 “(iv) SUBCLAUSE (IV) CERTIFICATION  
4 WITH RESPECT TO OTHER PATENTS.—

5 “(I) IN GENERAL.—If the appli-  
6 cant made a certification described in  
7 paragraph (2)(A)(vii)(IV) with respect  
8 to a patent not described in clause  
9 (iii) for which patent information was  
10 published by the Secretary under sub-  
11 section (c)(2)(D), the approval shall  
12 be made effective on the date that is  
13 45 days after the date on which the  
14 notice provided under paragraph  
15 (2)(B) was received, unless a civil ac-  
16 tion for infringement of the patent,  
17 accompanied by a motion for prelimi-  
18 nary injunction to enjoin the applicant  
19 from engaging in the commercial  
20 manufacture or sale of the drug, was  
21 filed on or before the date that is 45  
22 days after the date on which the no-  
23 tice was received, in which case the  
24 approval shall be made effective—

1 “(aa) on the date of a court  
2 action declining to grant a pre-  
3 liminary injunction; or

4 “(bb) if the court has grant-  
5 ed a preliminary injunction pro-  
6 hibiting the applicant from en-  
7 gaging in the commercial manu-  
8 facture or sale of the drug—

9 “(AA) on issuance by a  
10 court of a determination  
11 that the patent is invalid or  
12 is not infringed;

13 “(BB) on issuance by a  
14 court of an order revoking  
15 the preliminary injunction or  
16 permitting the applicant to  
17 engage in the commercial  
18 manufacture or sale of the  
19 drug; or

20 “(CC) on the date spec-  
21 ified in a court order under  
22 section 271(e)(4)(A) of title  
23 35, United States Code, if  
24 the court determines that  
25 the patent is infringed.

1                   “(II) COOPERATION.—Each of  
2                   the parties shall reasonably cooperate  
3                   in expediting a civil action under sub-  
4                   clause (I).

5                   “(III) EXPEDITED NOTIFICA-  
6                   TION.—If the notice under paragraph  
7                   (2)(B) contains an address for the re-  
8                   ceipt of expedited notification of a  
9                   civil action under subclause (I), the  
10                  plaintiff shall, on the date on which  
11                  the complaint is filed, simultaneously  
12                  cause a notification of the civil action  
13                  to be delivered to that address by the  
14                  next business day.”; and

15                  (2) by inserting after subparagraph (B) the fol-  
16                  lowing:

17                  “(C) FAILURE TO BRING INFRINGEMENT  
18                  ACTION.—If, in connection with an application  
19                  under this subsection, the applicant provides an  
20                  owner of a patent notice under paragraph  
21                  (2)(B) with respect to the patent, and the  
22                  owner of the patent fails to bring a civil action  
23                  against the applicant for infringement of the  
24                  patent on or before the date that is 45 days  
25                  after the date on which the notice is received,

the owner of the patent shall be barred from bringing a civil action for infringement of the patent in connection with the development, manufacture, use, offer to sell, or sale of the drug for which the application was filed or approved under this subsection.”.

(b) OTHER APPLICATIONS.—Section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) (as amended by section 9(a)(3)(A)(iii)) is amended—

(1) in paragraph (3)—

(A) in subparagraph (C)—

(i) by striking “(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A),” and inserting the following:

“(C) CLAUSE (iv) CERTIFICATION WITH RESPECT TO CERTAIN PATENTS.—If the applicant made a certification described in subsection (b)(2)(A)(iv) with respect to a patent (other than a patent that claims a process for manufacturing the listed drug) for which patent information was filed with the Secretary under paragraph (2)(A),”; and

(ii) by adding at the end the following: “The 30-month period provided



under the second sentence of this subparagraph shall not apply to a certification under subsection (b)(2)(A)(iv) made with respect to a patent for which patent information was filed with the Secretary under paragraph (2)(B).”; and

(B) by inserting after subparagraph (C) the following:

“(D) CLAUSE (iv) CERTIFICATION WITH RESPECT TO OTHER PATENTS.—

“(i) IN GENERAL.—If the applicant made a certification described in subsection (b)(2)(A)(iv) with respect to a patent not described in subparagraph (C) for which patent information was published by the Secretary under paragraph (2)(D), the approval shall be made effective on the date that is 45 days after the date on which the notice provided under subsection (b)(3) was received, unless a civil action for infringement of the patent, accompanied by a motion for preliminary injunction to enjoin the applicant from engaging in the commercial manufacture or sale of the drug, was filed on or before the date

1           that is 45 days after the date on which the  
2           notice was received, in which case the ap-  
3           proval shall be made effective—

4                   “(I) on the date of a court action  
5                   declining to grant a preliminary in-  
6                   junction; or

7                   “(II) if the court has granted a  
8                   preliminary injunction prohibiting the  
9                   applicant from engaging in the com-  
10                  mercial manufacture or sale of the  
11                  drug—

12                   “(aa) on issuance by a court  
13                   of a determination that the pat-  
14                   ent is invalid or is not infringed;

15                   “(bb) on issuance by a court  
16                   of an order revoking the prelimi-  
17                   nary injunction or permitting the  
18                   applicant to engage in the com-  
19                   mercial manufacture or sale of  
20                   the drug; or

21                   “(cc) on the date specified  
22                   in a court order under section  
23                   271(e)(4)(A) of title 35, United  
24                   States Code, if the court deter-

1                   mines that the patent is in-  
2                   fringed.

3                   “(ii) COOPERATION.—Each of the  
4                   parties shall reasonably cooperate in expe-  
5                   diting a civil action under clause (i).

6                   “(iii) EXPEDITED NOTIFICATION.—If  
7                   the notice under subsection (b)(3) contains  
8                   an address for the receipt of expedited no-  
9                   tification of a civil action under clause (i),  
10                  the plaintiff shall, on the date on which the  
11                  complaint is filed, simultaneously cause a  
12                  notification of the civil action to be deliv-  
13                  ered to that address by the next business  
14                  day.”; and

15                  (2) by inserting after paragraph (3) the fol-  
16                  lowing:

17                  “(4) FAILURE TO BRING INFRINGEMENT AC-  
18                  TION.—If, in connection with an application under  
19                  subsection (b)(2), the applicant provides an owner of  
20                  a patent notice under subsection (b)(3) with respect  
21                  to the patent, and the owner of the patent fails to  
22                  bring a civil action against the applicant for in-  
23                  fringement of the patent on or before the date that  
24                  is 45 days after the date on which the notice is re-  
25                  ceived, the owner of the patent shall be barred from

1 bringing a civil action for infringement of the patent  
2 in connection with the development, manufacture,  
3 use, offer to sell, or sale of the drug for which the  
4 application was filed or approved under subsection  
5 (b)(2).”.

6 (c) EFFECTIVE DATE.—

7 (1) IN GENERAL.—The amendments made by  
8 subsections (a) and (b) shall be effective with re-  
9 spect to any certification under subsection  
10 (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of  
11 the Federal Food, Drug, and Cosmetic Act (21  
12 U.S.C. 355) made after the date of enactment of  
13 this Act in an application filed under subsection  
14 (b)(2) or (j) of that section.

15 (2) TRANSITION PROVISION.—In the case of ap-  
16 plications under section 505(b) of the Federal Food,  
17 Drug, and Cosmetic Act (21 U.S.C. 355(b)) filed be-  
18 fore the date of enactment of this Act—

19 (A) a patent (other than a patent that  
20 claims a process for manufacturing a listed  
21 drug) for which information was submitted to  
22 the Secretary of Health and Human Services  
23 under section 505(b)(1) of the Federal Food,  
24 Drug, and Cosmetic Act (as in effect on the day  
25 before the date of enactment of this Act) shall

1 be subject to subsections (c)(3)(C) and  
 2 (j)(5)(B)(iii) of section 505 of the Federal  
 3 Food, Drug, and Cosmetic Act (as amended by  
 4 this section); and

5 (B) any other patent (including a patent  
 6 for which information was submitted to the  
 7 Secretary under section 505(c)(2) of that Act  
 8 (as in effect on the day before the date of en-  
 9 actment of this Act)) shall be subject to sub-  
 10 sections (c)(3)(D) and (j)(5)(B)(iv) of section  
 11 505 of the Federal Food, Drug, and Cosmetic  
 12 Act (as amended by this section).

13 **SEC. 5. EXCLUSIVITY FOR ACCELERATED GENERIC DRUG**  
 14 **APPLICANTS.**

15 (a) IN GENERAL.—Section 505(j)(5) of the Federal  
 16 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) (as  
 17 amended by section 4(a)) is amended—

18 (1) in subparagraph (B)(v), by striking sub-  
 19 clause (II) and inserting the following:

20 “(II) the earlier of—

21 “(aa) the date of a final de-  
 22 cision of a court (from which no  
 23 appeal has been or can be taken,  
 24 other than a petition to the Su-  
 25 preme Court for a writ of certio-

rari) holding that the patent that  
is the subject of the certification  
is invalid or not infringed; or

“(bb) the date of a settle-  
ment order or consent decree  
signed by a Federal judge that  
enters a final judgment and in-  
cludes a finding that the patent  
that is the subject of the certifi-  
cation is invalid or not in-  
fringed;”; and

(2) by inserting after subparagraph (C) the fol-  
lowing:

“(D) FORFEITURE OF 180-DAY PERIOD.—

“(i) DEFINITIONS.—In this subpara-  
graph:

“(I) APPLICATION.—The term  
‘application’ means an application for  
approval of a drug under this sub-  
section containing a certification  
under paragraph (2)(A)(vii)(IV) with  
respect to a patent.

“(II) FIRST APPLICATION.—The  
term ‘first application’ means the first

1 application to be filed for approval of  
2 the drug.

3 “(III) FORFEITURE EVENT.—

4 The term ‘forfeiture event’, with re-  
5 spect to an application under this sub-  
6 section, means the occurrence of any  
7 of the following:

8 “(aa) FAILURE TO MAR-  
9 KET.—The applicant fails to  
10 market the drug by the later of—

11 “(AA) the date that is  
12 60 days after the date on  
13 which the approval of the  
14 application for the drug is  
15 made effective under clause  
16 (iii) or (iv) of subparagraph  
17 (B) (unless the Secretary ex-  
18 tends the date because of ex-  
19 traordinary or unusual cir-  
20 cumstances); or

21 “(BB) if 1 or more civil  
22 actions have been brought  
23 against the applicant for in-  
24 fringement of a patent sub-  
25 ject to a certification under

1 paragraph (2)(A)(vii)(IV) or  
2 1 or more civil actions have  
3 been brought by the appli-  
4 cant for a declaratory judg-  
5 ment that such a patent is  
6 invalid or not infringed, the  
7 date that is 60 days after  
8 the date of a final decision  
9 (from which no appeal has  
10 been or can be taken, other  
11 than a petition to the Su-  
12 preme Court for a writ of  
13 certiorari) in the last of  
14 those civil actions to be de-  
15 cided (unless the Secretary  
16 extends the date because of  
17 extraordinary or unusual  
18 circumstances).

19 “(bb) WITHDRAWAL OF AP-  
20 PPLICATION.—The applicant with-  
21 draws the application.

22 “(cc) AMENDMENT OF CER-  
23 TIFICATION.—The applicant, vol-  
24 untarily or as a result of a settle-  
25 ment or defeat in patent litiga-



tion, amends the certification from a certification under paragraph (2)(A)(vii)(IV) to a certification under paragraph (2)(A)(vii)(III).

“(dd) FAILURE TO OBTAIN APPROVAL.—The applicant fails to obtain tentative approval of an application within 30 months after the date on which the application is filed, unless the failure is caused by—

“(AA) a change in the requirements for approval of the application imposed after the date on which the application is filed; or

“(BB) other extraordinary circumstances warranting an exception, as determined by the Secretary.

“(ee) FAILURE TO CHALLENGE PATENT.—In a case in which, after the date on which the applicant submitted the ap-

1 plication, new patent information  
2 is submitted under subsection  
3 (c)(2) for the listed drug for a  
4 patent for which certification is  
5 required under paragraph (2)(A),  
6 the applicant fails to submit, not  
7 later than the date that is 60  
8 days after the date on which the  
9 Secretary publishes the new pat-  
10 ent information under paragraph  
11 (7)(A)(iii) (unless the Secretary  
12 extends the date because of ex-  
13 traordinary or unusual cir-  
14 cumstances)—

15 “(AA) a certification  
16 described in paragraph  
17 (2)(A)(vii)(IV) with respect  
18 to the patent to which the  
19 new patent information re-  
20 lates; or

21 “(BB) a statement that  
22 any method of use claim of  
23 that patent does not claim a  
24 use for which the applicant  
25 is seeking approval under

1                   this subsection in accord-  
 2                   ance with paragraph  
 3                   (2)(A)(viii).

4                   “(ff) UNLAWFUL CON-  
 5                   DUCT.—The Federal Trade Com-  
 6                   mission determines that the ap-  
 7                   plicant engaged in unlawful con-  
 8                   duct with respect to the applica-  
 9                   tion in violation of section 1 of  
 10                  the Sherman Act (15 U.S.C. 1).

11                  “(IV) SUBSEQUENT APPLICA-  
 12                  TION.—The term ‘subsequent applica-  
 13                  tion’ means an application for ap-  
 14                  proval of a drug that is filed subse-  
 15                  quent to the filing of a first applica-  
 16                  tion for approval of that drug.

17                  “(ii) FORFEITURE OF 180-DAY PE-  
 18                  RIOD.—

19                  “(I) IN GENERAL.—Except as  
 20                  provided in subclause (II), if a for-  
 21                  feiture event occurs with respect to a  
 22                  first application—

23                         “(aa) the 180-day period  
 24                         under subparagraph (B)(v) shall

1 be forfeited by the first applicant;  
 2 and

3 “(bb) any subsequent appli-  
 4 cation shall become effective as  
 5 provided under clause (i), (ii),  
 6 (iii), or (iv) of subparagraph (B),  
 7 and clause (v) of subparagraph  
 8 (B) shall not apply to the subse-  
 9 quent application.

10 “(II) FORFEITURE TO FIRST  
 11 SUBSEQUENT APPLICANT.—If the sub-  
 12 sequent application that is the first to  
 13 be made effective under subclause (I)  
 14 was the first among a number of sub-  
 15 sequent applications to be filed—

16 “(aa) that first subsequent  
 17 application shall be treated as  
 18 the first application under this  
 19 subparagraph (including sub-  
 20 clause (I)) and as the previous  
 21 application under subparagraph  
 22 (B)(v); and

23 “(bb) any other subsequent  
 24 applications shall become effec-  
 25 tive as provided under clause (i),

1 (ii), (iii), or (iv) of subparagraph  
2 (B), but clause (v) of subpara-  
3 graph (B) shall apply to any such  
4 subsequent application.

5 “(iii) AVAILABILITY.—The 180-day  
6 period under subparagraph (B)(v) shall be  
7 available to a first applicant submitting an  
8 application for a drug with respect to any  
9 patent without regard to whether an appli-  
10 cation has been submitted for the drug  
11 under this subsection containing such a  
12 certification with respect to a different pat-  
13 ent.

14 “(iv) APPLICABILITY.—The 180-day  
15 period described in subparagraph (B)(v)  
16 shall apply to an application only if a civil  
17 action is brought against the applicant for  
18 infringement of a patent that is the subject  
19 of the certification.”.

20 (b) APPLICABILITY.—The amendment made by sub-  
21 section (a) shall be effective only with respect to an appli-  
22 cation filed under section 505(j) of the Federal Food,  
23 Drug, and Cosmetic Act (21 U.S.C. 355(j)) after the date  
24 of enactment of this Act for a listed drug for which no  
25 certification under section 505(j)(2)(A)(vii)(IV) of that

1 Act was made before the date of enactment of this Act,  
 2 except that if a forfeiture event described in section  
 3 505(j)(5)(D)(i)(III)(ff) of that Act occurs in the case of  
 4 an applicant, the applicant shall forfeit the 180-day period  
 5 under section 505(j)(5)(B)(v) of that Act without regard  
 6 to when the applicant made a certification under section  
 7 505(j)(2)(A)(vii)(IV) of that Act.

8 **SEC. 6. FAIR TREATMENT FOR INNOVATORS.**

9 (a) BASIS FOR APPLICATION.—Section 505 of the  
 10 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)  
 11 is amended—

12 (1) in subsection (b)(3)(B), by striking the sec-  
 13 ond sentence and inserting “The notice shall include  
 14 a detailed statement of the factual and legal basis of  
 15 the applicant’s opinion that, as of the date of the no-  
 16 tice, the patent is not valid or is not infringed, and  
 17 shall include, as appropriate for the relevant patent,  
 18 a description of the applicant’s proposed drug sub-  
 19 stance, drug formulation, drug composition, or meth-  
 20 od of use. All information disclosed under this sub-  
 21 paragraph shall be treated as confidential and may  
 22 be used only for purposes relating to patent adju-  
 23 dication. Nothing in this subparagraph precludes the  
 24 applicant from amending the factual or legal basis

1 on which the applicant relies in patent litigation.”;  
2 and

3 (2) in subsection (j)(2)(B)(ii), by striking the  
4 second sentence and inserting “The notice shall in-  
5 clude a detailed statement of the factual and legal  
6 basis of the opinion of the applicant that, as of the  
7 date of the notice, the patent is not valid or is not  
8 infringed, and shall include, as appropriate for the  
9 relevant patent, a description of the applicant’s pro-  
10 posed drug substance, drug formulation, drug com-  
11 position, or method of use. All information disclosed  
12 under this subparagraph shall be treated as con-  
13 fidential and may be used only for purposes relating  
14 to patent adjudication. Nothing in this subparagraph  
15 precludes the applicant from amending the factual  
16 or legal basis on which the applicant relies in patent  
17 litigation.”.

18 (b) INJUNCTIVE RELIEF.—Section 505(j)(5)(B) of  
19 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
20 355(j)(5)(B)) (as amended by section 4(a)(1)) is amend-  
21 ed—

22 (1) in clause (iii), by adding at the end the fol-  
23 lowing: “A court shall not regard the extent of the  
24 ability of an applicant to pay monetary damages as  
25 a whole or partial basis on which to deny a prelimi-

1 nary or permanent injunction under this clause.”;  
 2 and

3 (2) in clause (iv), by adding at the end the fol-  
 4 lowing:

5 “(IV) INJUNCTIVE RELIEF.—A court shall  
 6 not regard the extent of the ability of an appli-  
 7 cant to pay monetary damages as a whole or  
 8 partial basis on which to deny a preliminary or  
 9 permanent injunction under this clause.”.

10 **SEC. 7. BIOEQUIVALENCE.**

11 (a) IN GENERAL.—The amendments to part 320 of  
 12 title 21, Code of Federal Regulations, promulgated by the  
 13 Commissioner of Food and Drugs on July 17, 1991 (57  
 14 Fed. Reg. 17997 (April 28, 1992)), shall continue in effect  
 15 as an exercise of authorities under sections 501, 502, 505,  
 16 and 701 of the Federal Food, Drug, and Cosmetic Act  
 17 (21 U.S.C. 351, 352, 355, 371).

18 (b) EFFECT.—Subsection (a) does not affect the au-  
 19 thority of the Commissioner of Food and Drugs to amend  
 20 part 320 of title 21, Code of Federal Regulations.

21 (c) EFFECT OF SECTION.—This section shall not be  
 22 construed to alter the authority of the Secretary of Health  
 23 and Human Services to regulate biological products under  
 24 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301  
 25 et seq.). Any such authority shall be exercised under that



1 Act as in effect on the day before the date of enactment  
2 of this Act.

3 **SEC. 8. REPORT.**

4 (a) IN GENERAL.—Not later than the date that is  
5 5 years after the date of enactment of this Act, the Fed-  
6 eral Trade Commission shall submit to Congress a report  
7 describing the extent to which implementation of the  
8 amendments made by this Act—

9 (1) has enabled products to come to market in  
10 a fair and expeditious manner, consistent with the  
11 rights of patent owners under intellectual property  
12 law; and

13 (2) has promoted lower prices of drugs and  
14 greater access to drugs through price competition.

15 (b) AUTHORIZATION OF APPROPRIATIONS.—There is  
16 authorized to be appropriated to carry out this section  
17 \$5,000,000.

18 **SEC. 9. CONFORMING AND TECHNICAL AMENDMENTS.**

19 (a) SECTION 505.—Section 505 of the Federal Food,  
20 Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

21 (1) in subsection (a), by striking “(a) No per-  
22 son” and inserting “(a) IN GENERAL.—No person”;

23 (2) in subsection (b)—

24 (A) by striking “(b)(1) Any person” and  
25 inserting the following:

1 “(b) APPLICATIONS.—

2 “(1) REQUIREMENTS.—

3 “(A) IN GENERAL.—Any person”;

4 (B) in paragraph (1)—

5 (i) in the second sentence—

6 (I) by redesignating subpara-  
7 graphs (A) through (F) as clauses (i)  
8 through (vi), respectively, and adjust-  
9 ing the margins appropriately;

10 (II) by striking “Such persons”  
11 and inserting the following:

12 “(B) INFORMATION TO BE SUBMITTED  
13 WITH APPLICATION.—A person that submits an  
14 application under subparagraph (A)”;

15 (III) by striking “application”  
16 and inserting “application—”;

17 (ii) by striking the third through fifth  
18 sentences; and

19 (iii) in the sixth sentence—

20 (I) by striking “The Secretary”  
21 and inserting the following:

22 “(C) GUIDANCE.—The Secretary”; and

23 (II) by striking “clause (A)” and  
24 inserting “subparagraph (B)(i)”; and

25 (C) in paragraph (2)—

1 (i) by striking “clause (A) of such  
 2 paragraph” and inserting “paragraph  
 3 (1)(B)(i)”;

4 (ii) in subparagraphs (A) and (B), by  
 5 striking “paragraph (1) or”; and

6 (iii) in subparagraph (B)—

7 (I) by striking “paragraph  
 8 (1)(A)” and inserting “paragraph  
 9 (1)(B)(i)”;

10 (II) by striking “patent” each  
 11 place it appears and inserting  
 12 “claim”; and

13 (3) in subsection (c)—

14 (A) in paragraph (3)—

15 (i) in subparagraph (A)—

16 (I) by striking “(A) If the appli-  
 17 cant” and inserting the following:

18 “(A) CLAUSE (i) OR (ii) CERTIFICATION.—

19 If the applicant”; and

20 (II) by striking “may” and in-  
 21 serting “shall”;

22 (ii) in subparagraph (B)—

23 (I) by striking “(B) If the appli-  
 24 cant” and inserting the following:

- 1                   “(B) CLAUSE (iii) CERTIFICATION.—If the
- 2                   applicant”; and
- 3                   (II) by striking “may” and in-
- 4                   serting “shall”;
- 5                   (iii) by redesignating subparagraph
- 6                   (D) as subparagraph (E); and
- 7                   (iv) in subparagraph (E) (as redesign-
- 8                   ated by clause (iii)), by striking “clause
- 9                   (A) of subsection (b)(1)” each place it ap-
- 10                  pears and inserting “subsection
- 11                  (b)(1)(B)(i)”; and
- 12                  (B) by redesignating paragraph (4) as
- 13                  paragraph (5); and
- 14                  (4) in subsection (j)—
- 15                  (A) in paragraph (2)(A)—
- 16                   (i) in clause (vi), by striking “clauses
- 17                   (B) through ((F))” and inserting “sub-
- 18                   clauses (ii) through (vi) of subsection
- 19                   (b)(1)”;
- 20                   (ii) in clause (vii), by striking “(b)
- 21                   or”; and
- 22                   (iii) in clause (viii)—
- 23                   (I) by striking “(b) or”; and

1 (II) by striking “patent” each  
 2 place it appears and inserting  
 3 “claim”; and

4 (B) in paragraph (5)—

5 (i) in subparagraph (B)—

6 (I) in clause (i)—

7 (aa) by striking “(i) If the  
 8 applicant” and inserting the fol-  
 9 lowing:

10 “(i) SUBCLAUSE (I) OR (II) CERTIFI-  
 11 CATION.—If the applicant”; and

12 (bb) by striking “may” and  
 13 inserting “shall”;

14 (II) in clause (ii)—

15 (aa) by striking “(ii) If the  
 16 applicant” and inserting the fol-  
 17 lowing:

18 “(i) SUBCLAUSE (III) CERTIFI-  
 19 CATION.—If the applicant”; and

20 (bb) by striking “may” and  
 21 inserting “shall”;

22 (III) in clause (iii), by striking  
 23 “(2)(B)(i)” each place it appears and  
 24 inserting “(2)(B)”; and

1 (IV) in clause (v) (as redesignig-  
 2 nated by section 4(a)(1)(B)), by strik-  
 3 ing “continuing” and inserting “con-  
 4 taining”; and

5 (ii) by redesignating subparagraphs  
 6 (C) and (D) as subparagraphs (E) and  
 7 (F), respectively.

8 (b) SECTION 505A.—Section 505A of the Federal  
 9 Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is  
 10 amended—

11 (1) in subsections (b)(1)(A)(i) and  
 12 (c)(1)(A)(i)—

13 (A) by striking “(c)(3)(D)(ii)” each place  
 14 it appears and inserting “(c)(3)(E)(ii)”; and

15 (B) by striking “(j)(5)(D)(ii)” each place  
 16 it appears and inserting “(j)(5)(F)(ii)”; and

17 (2) in subsections (b)(1)(A)(ii) and  
 18 (c)(1)(A)(ii)—

19 (A) by striking “(c)(3)(D)” each place it  
 20 appears and inserting “(c)(3)(E)”; and

21 (B) by striking “(j)(5)(D)” each place it  
 22 appears and inserting “(j)(5)(F)”; and

23 (3) in subsections (e) and (l)—

24 (A) by striking “505(c)(3)(D)” each place  
 25 it appears and inserting “505(c)(3)(E)”; and

1                   (B) by striking “505(j)(5)(D)” each place  
2                   it appears and inserting “505(j)(5)(F)”; and  
3                   (4)     in     subsection     (k),     by     striking  
4                   “505(j)(5)(B)(iv)” and inserting “505(j)(5)(B)(v)”.

5           (c) SECTION 527.—Section 527(a) of the Federal  
6 Food, Drug, and Cosmetic Act (21 U.S.C. 360cc(a)) is  
7 amended in the second sentence by striking “505(c)(2)”  
8 and inserting “505(c)(1)(B)”.

○